

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	M.D.L. No. 1456
AVERAGE WHOLESALE PRICE)	Civil Action No. 01-12257-PBS
LITIGATION)	

MEMORANDUM AND ORDER

May 13, 2003

Saris, U.S.D.J.

I. INTRODUCTION

In this proposed class action, plaintiffs allege that numerous pharmaceutical companies fraudulently overstate the published "average wholesale price" ("AWP") of many of their prescription drugs, which results in inflated payments for such drugs by beneficiaries of the federal Medicare Part B program (through beneficiary co-payments), private health and welfare plans, and other end-payors.¹

¹ The complaint names the following companies as defendants (corporate groupings are separated by semicolon): Abbot Laboratories; Amgen, Inc.; "AstraZeneca," which includes, Zeneca, Inc., AstraZeneca US, and AstraZeneca Pharmaceuticals L.P.; "The Aventis Group," which includes, Aventis Pharmaceuticals, Inc., Hoechst Marion Roussel, Inc., and Aventis Behring, LLC; "Baxter," which includes, Baxter International Inc. and Baxter Healthcare Corporation; Bayer Corp.; "The Boehringer Group," which includes, Boehringer Ingelheim Corp, Ben Venue Laboratories, Inc., and Bedford Laboratories; B. Braun Medical Inc.; "The BMS Group" which includes, Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc.; Dey, Inc.; "The Fujisawa Group" which includes, Fujisawa Healthcare, Inc. and Fujisawa U.S.A., Inc.; "The GSK Group" which

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The Master Consolidated Complaint asserts claims under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C §§ 1964(c) (Counts I-IV), and the consumer protection statutes of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, and Washington (Count V). Plaintiffs also seek declaratory relief on the claim that reporting AWP's above the actual average wholesale price for various drugs is unlawful. (Counts VI and VII.)² The plaintiffs bring this action on behalf of themselves and two Classes: Class One, the Medicare Part B co-payor class,³ and Class Two, the third-party payor class.⁴

includes, GlaxoSmithKline, P.L.C., SmithKline Beecham Corp., and Glaxo Wellcome, Inc.; Hoffman-La Roche, Inc.; Immunex Corp.; "The Johnson & Johnson Group" which includes, Johnson & Johnson, Centocor, Inc. and Ortho Biotech; Merck & Co., Inc.; Pfizer, Inc.; "The Pharmacia Group" which includes, Pharmacia Corp. and Pharmacia & Upjohn, Inc.; "The Schering-Plough Group" which includes, Schering-Plough Corp. and Warrick Pharmaceuticals Corp.; "The Sicor Group," which includes, Sicor, Inc., Gensia, Inc., and Gensia Sicor Pharmaceuticals, Inc.; and Watson Pharmaceuticals, Inc.

² The Judicial Panel on Multidistrict Litigation ordered all related cases transferred to this District for coordinated and consolidated pre-trial proceedings.

³ Class One includes: "All persons or entities who, for purposes other than resale and during the Class Period, paid for the purchase of a prescription drug manufactured by a Defendant Drug Manufacturer, which payment constituted a contribution toward the Medicare Part B co-payment." (§ 333.) Counts I and II assert claims on behalf of Class One members only with respect to Medicare Part B covered drugs.

⁴ Class 2 Two includes: "All Third-Party Payors that, during the Class Period, contracted with a PBM or other

Acknowledging that their AWP's represent only "undiscounted sticker prices," and not actual average wholesale prices, defendants have jointly moved to dismiss on the following grounds: (1) that the court should abstain because this dispute involves a legislative question; (2) that the plaintiffs fail to allege viable RICO enterprises; and (3) that the state law claims are preempted by the Medicare Act, 42 U.S.C. § 1395-1395qqq, and the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001-1461. Individual defendants have raised company-specific grounds for dismissal.

After hearing and extensive briefing, the Court ALLOWS the motion to dismiss the RICO claims and DENIES the motion to dismiss the state claims on preemption grounds. The Court also dismisses (1) all the association plaintiffs on the ground they lack standing, (2) all claims regarding drugs that are not identified by name with a specified fraudulent AWP, and (3) certain companies from which no plaintiff claims to have purchased a drug with an inflated AWP. The dismissal will go into effect in 30 days if there is no motion to amend.

intermediary to, based on a "discount" off of AWP, provide to its participants a brand name prescription drug manufactured by a Defendant Drug Manufacturer." (§333) Counts III and IV are brought on behalf of Class Two members against some of the defendants for unlawful conduct associated with brand name prescription drugs.

II. STANDARD OF REVIEW

Generally, for purposes of a motion to dismiss the Court takes as true "the well-pleaded facts as they appear in the complaint, extending [the] plaintiff[s] every reasonable inference in [their] favor." Coyne v. City of Somerville, 972 F.2d 440, 442-43 (1st Cir. 1992) (citing Correa-Martinez v. Arrillaga-Belendez, 903 F.2d 49, 51 (1st Cir. 1990)). A complaint should not be dismissed under Fed. R. Civ. P. 12(b)(6) unless "'it appears beyond doubt that the plaintiff[s] can prove no set of facts in support of [their] claim which would entitle [them] to relief.'" Roeder v. Alpha Indus., Inc., 814 F.2d 22, 25 (1st Cir. 1987) (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). As to the RICO claims, the Court is mindful of the First Circuit's instruction that while "the pleadings should generally be construed liberally . . . a greater level of specificity is required in RICO cases." Bessette v. Avco Fin. Servs., Inc., 230 F.3d 439, 443 (1st Cir. 2000) (citing Garita Hotel Ltd. P'ship v. Ponce Fed. Bank., 958 F.2d 15, 17 & n. 1 (1st Cir. 1992)).

III. FACTUAL BACKGROUND

The consolidated class action complaint alleges the following facts, many of which are in dispute.

Medicare is the federal insurance program that pays for the medical care of persons 65 and older. See 42 U.S.C. §§ 1395 -

1395qqq. The Medicare program is administered by the Center for Medicare and Medicaid Services ("CMS"), which is under the authority of the Secretary of Health and Human Services. Medicare Part B establishes an insurance program to pay for physicians' services. See id. at §§1395j-1395w. Medicare generally does not cover the cost of prescription drugs that a beneficiary self-administers (for example, by swallowing the drug). It does cover approximately 450 outpatient drugs, including ones that are administered by a doctor, and certain oral anti-cancer drugs. (Compl. ¶ 143.)

Through the Medicare Part B program, the federal government reimburses health care providers, such as physicians, for up to 80 percent of the allowable cost of certain prescription drugs that they administer directly to patients. The remaining 20 percent is paid by the Medicare Part B beneficiary, as a co-payment. 42 U.S.C. § 1395l(o); (Compl. ¶ 149.) The drug reimbursement rates are based on "the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological." 42 C.F.R. § 405.517; see also 42 U.S.C. § 1395u(o) ("...the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.").

In setting reimbursement rates, the Medicare program uses the AWP's generated by the pharmaceutical industry. There are no

regulations describing how AWP's are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWP's directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWP's in trade publications, which are then used by the government, as well as private health plans.⁵ The publishing companies do not independently review the figures for accuracy. The figures are not filed with the CMS.

The pharmaceutical companies vastly overstate the AWP's of many drugs in the data they provide to the trade publications. For example, for one drug called "Acyclovir," defendant Abbott Laboratories reports an AWP to the "Red Book" publication of \$1047.38, while the actual average wholesale price is only \$349.05. In some instances the reported AWP is more than 10,000 percent higher than the actual AWP. The following table, drawn from the complaint (¶ 190), provides just a sampling of AWP overstatements by Abbott:

⁵ The major publications include the Drug Topics Red Book (the "Red Book"), American Druggist First Databank Annual Director of Pharmaceuticals, Essential Director of Pharmaceuticals ("the Blue Book") and the Master Drug Database. These books report AWP's for various dosages of thousands of prescription drugs.

Drug	Abbott's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Spread
Acetylcysteine	\$35.87	\$21.90	\$13.97	64%
Acyclovir	\$1,047.38	\$349.05	\$698.33	200%
Amikacin Sulfate	\$995.84	\$125.00	\$870.84	697%
Calcitriol (Calcijex)	\$1,390.66	\$1,079.00	\$311.66	29%
Cimetidine Hydrochloride	\$214.34	\$35.00	\$179.34	512%
Clindamycin Phosphate	\$340.52	\$75.35	\$265.17	352%
Dextrose	\$239.97	\$3.91	\$236.06	6,037%
Dextrose Sodium Chloride	\$304.38	\$1.93	\$302.45	15,671%
Diazepam	\$28.50	\$2.03	\$26.47	1,304%
Furosemide	\$74.52	\$14.38	\$60.14	418%
Gentamicin Sulfate	\$64.42	\$5.51	\$63.91	12,531%
Heparin Lock Flush	\$38.30	\$13.60	\$24.70	182%
Metholprednisolone Sodium Succinate	\$34.08	\$2.30	\$31.78	1,382%
Sodium Chloride	\$670.89	\$3.22	\$667.67	20,735%
Tobramycin Sulfate	\$150.52	\$2.94	\$147.58	5,020%
Vancomycin Hydrochloride	\$382.14	\$4.98	\$377.16	7,574%

The complaint alleges by name more than 100 drugs, from numerous pharmaceutical companies, with inflated AWP's.

This overstatement in the reporting creates a "spread," as seen in the table above, between the actual cost of a drug to a health care provider, and the reimbursement paid to the provider by the federal government. It also inflates the co-payments made by consumers. Defendants actively market this "spread" to providers, who are encouraged to buy drugs from defendants at the highly "discounted" actual prices, and are urged to keep the reimbursement and co-payment spreads for themselves. This

practice increases sales and a drug manufacturer's market share of the drug.

For some defendants, the AWP scheme is not the only mechanism used to create the artificial "spreads." Another method involves the provision of "free samples" to health providers who are sometimes encouraged to bill their customers for the samples as they would any other drug. This "free sample" scheme lowers the providers' overall costs while not reducing the amount they receive in reimbursements from the federal government, or co-payments from consumers, which remain tied to the reported AWP's. Other fraudulent pricing practices include off-invoice pricing, phony consulting fees, as well as debt forgiveness, rebates, and grants. All of these incentives were designed to lower the providers' net cost of purchasing the drugs.

Plaintiff union and employee health benefit plans contract with drug plan managers, known as Pharmacy Benefit Managers ("PBMs"), which operate as intermediaries between the pharmaceutical companies and the private health plans. These PBMs set prices on their formularies - their drug fee lists - based on the AWP figures reported in the same trade publications used by the Medicare program, less a certain percentage discount. Again, defendants market the same pricing and reporting "spread" to PBMs that they do to individual health care providers serving

Medicare patients. The PBMs are offered drugs at highly "discounted" actual prices while charging the private health plans fees based on the inflated AWP. The PBMs benefit by keeping the "spread" for themselves and the pharmaceutical companies benefit because PBMs are drawn to keeping on their formularies drugs from those companies offering the most lucrative "spreads."

IV. DISCUSSION

A. Prudential Abstention

Defendants concede that the "national average wholesale price" figures upon which Medicare Part B reimbursements and co-payments are based are not the actual average of wholesale prices they charge for their drugs. Nonetheless, pointing to legislative hearings and statements on AWP, they contend that Congress knows that the AWP they report represent only an "un-discounted sticker price" that has no direct relation to the actual average price they charge for their drugs, and that Congress has acceded to this widespread pricing and reporting practice.⁶

⁶ Plaintiffs' dispute defendants' claim that the government has acquiesced in defendants' practices with respect to AWP. Most recently, plaintiffs have submitted as "supplemental authority" a document prepared by the Department of Health and Human Services, Office of the Inspector General, titled "Compliance Program Guidance for Pharmaceutical Manufacturers" (dated April 2003), which contains the following statement: "[I]t is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one

Drawing on the policies underpinning the political question doctrine, and urging "prudential abstention," defendants argue that it would be an unwarranted excursion into the legislative domain for this Court to hold defendants' practices unlawful when Congress has acquiesced in these practices. See generally Warth v. Seldin, 422 U.S. 490, 499-500, 95 S.Ct. 2197, 2205 (1975) (discussing limitations on judicial intervention that involve matters of "judicial self-governance."); Baker v. Carr, 369 U.S. 186, 210, 82 S.Ct. 691, 706 (1961) (noting that the political question doctrine operates as a prudential limitation on the courts review of other branches of government; it is "primarily a function of the separation of powers").

However, "not every matter touching on politics is a political question." Japan Whaling Ass'n v. Am. Cetacean Soc'y, 478 U.S. 221, 229-30, 106 S.Ct. 2860, 2865-66 (1986). "It goes without saying that interpreting congressional legislation is a recurring and accepted task for the federal courts." Id.; see also Bureau of Alcohol, Tobacco and Firearms v. Fed. Labor Relations Auth., 464 U.S. 89, 98 n. 8, 104 S.Ct. 439, 445 n. 8 (1983) (observing that "deciding what a statute means" is "the quintessential judicial function"); United States v. 29 Cartons of *** An Article of Food, 987 F.2d 33, 38 (1st Cir 1993) (same).

purpose is to manipulate the 'spread' to induce customers to purchase its product." Id. at 27.

The fact that congressional hearings have been held, congressional reports generated, and executive branch statements on the AWP issued, without follow-up legislative action,⁷ does not mandate judicial retreat from this heartland task of construing statutory language. Cf. Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 306, 108 S.Ct. 1145, 1154 (1988) (indicating "reluct[ance] to draw inferences from Congress' failure to act.").

The primary authority on which defendants rely for their prudential abstention argument, Stephenson v. Shalala, 87 F.3d 350 (9th Cir. 1996), is not on point. In Stephenson, the Ninth Circuit upheld the Secretary's interpretation of a statutory provision that health providers charge certain Medicare hospital patients a reasonable fee, relying, in part, on Congressional acquiescence in her interpretation. Id. at 356-57. The Stephenson Court exercised its duty to interpret the statute at issue there by applying appropriate canons of construction: the case is not an example of a court abstaining from statutory construction. See id.

⁷ Defendants make much of the fact that Congress enacted legislation barring the Secretary of Health and Human Services from "directly or indirectly decreas[ing] the rates of reimbursement" for drugs covered by Part B until the Comptroller General studied the issue of medical drug reimbursement, Medicare, and Medicaid and Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. No. 106-554, §429(c), 114 Stat. 2763 (2000). However, the study was completed in September 2001.

I decline to dismiss the action on prudential abstention grounds.

B. RICO Allegations

1. The Enterprise Requirement

Plaintiffs allege that defendants engaged in a pattern of racketeering activity by accomplishing the fraudulent AWP pricing scheme through the use of interstate mails and wire communications in violation of 18 U.S.C. § 1962(c).⁸ Defendants argue that the RICO claims must be dismissed because plaintiffs do not allege a viable RICO enterprise.⁹

To state a RICO claim under § 1962(c), a plaintiff must allege four elements: "(1) conduct; (2) of an enterprise; (3) through a pattern; (4) of racketeering activity." See Libertad v. Welch, 53 F.3d 428, 441 (1st Cir. 1995).

⁸ 18 U.S.C. § 1962(c) provides:

It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity

⁹ Defendants also argue that the claims should be dismissed because plaintiffs cannot demonstrate violations of the mail and wire fraud statutes, and because the plaintiffs' injuries were not caused directly by the conduct of any of the defendants. However, I do not discuss these arguments in light of the dismissal for failure to allege an enterprise.

The term "enterprise" is defined by the statute:

"enterprise" includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.

18 U.S.C § 1961(4). In interpreting the RICO "enterprise" requirement, the Supreme Court has explained that "[t]here is no restriction upon the associations embraced by the definition: an enterprise includes any union or group of individuals associated in fact." United States v. Turkette, 452 U.S. 576, 580, 101 S.Ct. 2524, 2527 (1981). The enterprise concept is not unbounded, however, because an enterprise must be "an entity for present purposes a group of persons associated together for a common purpose of engaging in a course of conduct." Id. at 583, 101 S.Ct. at 2528 (emphasis added). An enterprise is "proved by evidence of an ongoing organization, formal or informal, and by evidence that the various associates function as a continuing unit." Id. "While 'enterprise' and 'pattern of racketeering activity' are separate elements of a RICO offense, proof of these two elements need not be separate or distinct but may in fact 'coalesce.'" United States v. Patrick, 248 F.3d 11, 19 (1st Cir. 2001) (citing Turkette, 452 U.S. at 583, 101 S.Ct. at 2528).

"[T]wo or more legal entities can form or be part of an association-in-fact RICO enterprise." (first emphasis added) United States v. London, 66 F.3d 1227, 1243 (1st Cir. 1995); see

also River City Markets, Inc. v. Fleming Foods West, Inc., 960 F.2d 1458, 1462 (9th Cir. 1992) ("Virtually every business contract can be called an 'association in fact.'"); VNA Plus, Inc. v. Apria Healthcare Group, Inc., 29 F. Supp.2d 1253, 1259 (D. Kan. 1998) ("It is well established that no formal legal entity is required to create a RICO enterprise -- an informal association between two contracting businesses will suffice."); cf. Cedric Kushner Promotions v. King, 533 U.S. 158, 163, 121 S.Ct. 2087, 2091 (2001) (an association-in-fact enterprise can be comprised of only a corporation and its principal owner).

To make a claim out under RICO, the First Circuit has "consistently held that the same entity cannot do 'double duty' as both the RICO Defendant and the RICO Enterprise." Libertad, 53 F.3d at 442 (citing Miranda v. Ponce Fed. Bank, 948 F.2d 41, 44-45 (1st Cir. 1991)); see also Cedric Kushner Promotions, 533 U.S. at 161, 121 S.Ct. at 2090 (2001) (holding that the same party cannot serve as both the RICO defendant and the RICO enterprise).

Some circuits have held that a RICO enterprise must exhibit an "'ascertainable structure distinct from that inherent in the conduct of a pattern of racketeering activity.'" Patrick, 248 F.3d at 18 (quoting United States v. Bledsoe, 674 F.2d 647, 665 (8th Cir. 1982)). The First Circuit, however, has declined to define a criminal enterprise under 18 U.S.C. § 1962(c) as

requiring an ascertainable structure. See Patrick, 248 F.3d at 18. Instead, to establish an association in fact enterprise, plaintiff must show that the associated groups "constitute a larger unit, over and above their separate structures and operations." Libertad, 53 F.3d at 442.

The First Circuit has considered several factors in determining whether a RICO association-in-fact enterprise has been properly asserted: (1) whether the associates have a common purpose, see id. at 442-443; (2) whether there is "systematic linkage, such as overlapping leadership, structured or financial ties or continuing coordination," id. at 443; (3) whether there is a common communication network for sharing information on a regular basis, see id. at 444; (5) whether the associates hold meetings and sessions where important discussions take place, see Patrick, 248 F.3d at 19; (6) whether the associates wear common colors, signs or insignia to make the group identifiable, see id.; and (7) whether the group conducted common training and instruction, see id. None of these factors is dispositive.

2. The AWP Enterprises (¶¶ 346-350)

Plaintiffs allege twenty-one separate "AWP Enterprises," each consisting of a single defendant pharmaceutical company and all the medical providers that prescribe its drugs with a reported AWP. The complaint describes these enterprises as "associations-in-fact consisting of (a) various and independent

medical providers who prescribed Covered Drugs for which a Defendant Drug Manufacturer reported an AWP, and (b) a Defendant Drug Manufacturer, including its directors, employees, and agents." (Compl. ¶ 346.) As one example of this type of enterprise, it alleges "The Abbott Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Abbot reported an AWP, and Defendant Abbott, including its directors, employees and agents." (¶ 350.) The providers are those who sought co-payments from members of Class One (¶ 347.) Further, the providers, according to the complaint, are aware not only of the drug manufacturers' scheme, but are also "aware of the involvement of other similarly-situated providers in that fraudulent and unlawful scheme." (¶ 348.)

Plaintiffs essentially allege that each enterprise takes a hub-and-spoke design, with an individual drug manufacturer at the center dealing independently with each individual provider as the spoke. Put another way, plaintiffs allege that a doctor in Massachusetts and a doctor in Minnesota are part of the same RICO enterprise if they both prescribe Abbot's drug Acyclovir and collect a co-payment based on its AWP. The common purpose, according to plaintiffs, is that universal elixir -- greed.

Defendants argue that this hub-and-spoke configuration fails to allege a RICO enterprise. In an analogous context, the

Supreme Court has rejected a similar alleged hub-and-spoke conspiracy which had a pattern of separate spokes meeting at the common center without "the rim of the wheel to enclose the spokes." See Kotteakos v. United States, 328 U.S. 750, 769, 66 S.Ct. 1239, 1250 (1946) (holding that hub-and-spoke conspiracy in which one person arranged fraudulent loans from the Federal Housing Authority for eight different people constituted not one but eight separate conspiracies, each requiring its own proof for conviction). The Court cautioned against confusing "the common purpose of a single enterprise with the several, though similar, purposes of numerous separate enterprises of like character." Id.

Most courts have found that complaints alleging hub-and-spoke enterprises fail to satisfy the RICO enterprise requirement. See VanDenBroeck v. CommonPoint Mortg. Co., 210 F.3d 696, 700 (6th Cir. 2000) (rejecting a RICO enterprise involving defendant bank and a series of sub-lenders with whom the bank associated, because there were no allegations of a mechanism by which this group "conducted its affairs or made decisions"); New York Auto. Ins. Plan v. All Purpose Agency & Brokerage, Inc., 97-CV-3164, RICO Bus. Disp. Guide 9611, 1998 WL 695869 at *6 (S.D.N.Y. Oct. 6, 1998) (rejecting a hub-and-spoke enterprise in which auto-insurer conspired with individual clients to provide them lower insurance rates, without any

evident association between the clients; stating "Such a series of discontinuous independent frauds is not an 'enterprise.' Each is a single two-party conspiracy."); First Nationwide Bank v. Gelt Funding, Corp., 820 F.Supp. 89, 98 (S.D.N.Y. 1993) (holding that hub-and-spoke scheme is not an enterprise); Blue Cross and Blue Shield of Ala. v. Caremark, Inc., 98-CV-1285, RICO Bus. Disp. Guide 9828, 1999 WL 966434 at *8 (N.D. Ill. 1999) (rejecting enterprise theory in RICO insurance-fraud claim involving health providers because "[p]laintiffs fail to allege how this large and geographically diverse group of almost 3,000 independent physicians and entities acted in concert with one another . . . there is no indication that the individual [providers] were even aware of each other's existence."); Blue Cross of Cal. v. Smithkline Beecham Clinical Labs., Inc., 62 F. Supp.2d 544, 551-53 (D. Conn. 1998) (rejecting proposed enterprise consisting of insurer and, among others, thousands of doctors, where there was no evidence doctors were even aware of alleged kickback scheme). But see Fidelity Funding of Cal., Inc. v. Reinhold, 79 F.Supp.2d 110, 126 (E.D.N.Y. 1997) ("[Plaintiff] has alleged in it's Complaint a 'hub-and-spoke' arrangement, where Micro and Maxum served as the twin hubs and other defendants . . . served as the spokes. Whether or not this alleged arrangement adequately constitutes a non-RICO

conspiracy . . . it is sufficient to constitute a RICO enterprise.").

Plaintiffs rely heavily on In re Managed Care Litig., 185 F. Supp.2d 1310 (S.D. Fla. 2002). There the plaintiffs alleged several enterprises consisting of each of the defendant managed care insurance companies together with "the [d]efendant's health plans, and the primary physicians, medical specialists, medical laboratories, hospitals, outpatient centers, pharmacies, [and] home health agencies who contract with the [d]efendant." Id. at 1323. The district court found that a RICO enterprise existed because these associates actually constituted a "network" of inter-related health care providers, and moreover that the defendants had promoted the association as a "network" to plaintiffs, who complained of misrepresentations in their insurance coverage. See id.

Here, however, plaintiffs have not alleged an association in fact between a specific pharmaceutical company and a specific medical care provider (or a specific network of providers), that forms a continuing unit with a common purpose. Rather, they assert a series of enterprises, each consisting of hundreds or thousands of medical care providers whose only relationship to each other is that they all prescribe a covered drug with an AWP. Plaintiffs point out correspondence and other communications among the members of each of these alleged AWP enterprises,

including instructions from the pharmaceutical companies to the doctors concerning how to facilitate and conceal the alleged racketeering scheme. (See ¶¶ 161, 162, 175, 349.) Most of the mass marketing documents concern efforts by the companies to market "the spread" - between their actual prices and their reported AWP's - directly to the individual providers. (See ¶¶ 200, 213, 262, 296, 297, 303, 320, 349.) The documents as described do not allege a network among all the members of these alleged enterprises.

The complaint makes no allegation that all doctors who prescribe a pharmaceutical company's drug have associated together with each other and the drug company as an entity with a common fraudulent purpose, or that there is any common communication network, decision-making process, or organizational structure. The allegation that each provider was aware that there were likely other providers engaged in parallel schemes is insufficient to establish an association-in-fact RICO enterprise. In short, to use the Supreme Court's parlance, there was no rim to connect the spokes. At best, there were multiple and separate enterprises of like character. In sum, I conclude that plaintiffs have failed to allege facts that establish the RICO enterprise requirement through the "AWP Enterprises."

3. Pharmacy Benefit Managers ("PBM") Enterprises (¶¶ 429-431)

Next, plaintiffs allege the existence of Pharmacy Benefit

Manager Enterprises ("PBM Enterprises"), comprised of each individual drug manufacturer and all the Pharmacy Benefit Managers that exploit the "spread" between the reported AWP and the actual price of covered drugs. Sixteen different PBM enterprises are named. Each of the PBM Enterprises is said to be comprised of an individual drug company at the hub (i.e. Abbot, Amgen, etc.) and a number of unnamed pharmacy benefit managers as spokes. Again, however, the complaint fails to allege facts which would support an entity consisting of all the PBMs joined with a drug company in a common purpose.

4. Publisher Enterprises (¶¶ 375-77, 402-404)

The "Publisher Enterprises" present an even weaker theory. Plaintiffs allege that the Publisher Enterprises were associations-in-fact comprised of each of the defendants and the publishers that reported their AWP. There is no allegation that the publishing companies even benefitted from the "spread" scheme other than by the profits generated for publishing data provided to them. Again, plaintiffs identify each of these hub-and-spoke enterprises by the name of a pharmaceutical company (e.g. "Abbot Publisher Enterprise," etc.) and claim that these enterprises consist of the company and each of the major publishers that reported the AWP provided to them by the company as the spokes. Twenty-one such enterprises are named. The same twin problems of

connectedness and common purpose arise with respect to these enterprises.

**5. Third-Party Payor / Victim Enterprises
(¶¶ 351, 378, 405, 432)**

The Class Two plaintiffs allege that their employee health benefit plans are "enterprises" which were victimized when they made fraudulently inflated payments for drugs, based on defendants' falsely inflated AWP's. (¶ 359.) The third-party payor plaintiffs are the Board of Trustees of Carpenters and Millrights of Houston and Vicinity Welfare Trust Fund, Teamsters Health & Welfare Fund of Philadelphia, Twin Cities Bakery Workers Health and Welfare Fund, and United Food and Commercial Workers Unions and Employees Midwest Benefits Funds. Plaintiffs contend that these third-party payors satisfy the RICO enterprise requirement because they are "victim enterprises." This "victim enterprise" theory requires a different legal analysis.

The major purpose of RICO is to protect legitimate business enterprises from infiltration by racketeers. See Turkette, 452 U.S. at 591, 101 S.Ct. at 2532. The enterprise element may be satisfied by alleging a legitimate enterprise that was victimized by a racketeering scheme. See Aetna Cas. Sur. Co. v. P & B Autobody, 43 F.3d 1546, 1558 (1st Cir. 1994) (holding that an insurance company that was victim of racketeering activity involving company insiders satisfied enterprise requirement of RICO); United States v. Boylan, 898 F.2d 230, 243 (1st Cir. 1990)

(finding that the Boston Police Department was a victim enterprise because its affairs were interfered with through racketeering in the form of bribes), cert. denied, 498 U.S. 849, 111 S.Ct. 139 (1990).

To succeed in their RICO claim, however, plaintiffs must show not just the existence of a victim-enterprise, but that defendants "conduct[ed] or participat[ed], directly or indirectly, in the conduct of such enterprises affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

The Supreme Court has explained that "to conduct or participate, directly or indirectly, in the conduct" of an enterprise, "one must participate in the operation or management of the enterprise itself." Reves v. Ernst & Young, 507 U.S. 170, 185, 113 S.Ct. 1163, 1173 (1993). "[R]ICO liability is not limited to those with a formal position in the enterprise, but some part in directing the enterprise's affairs is required." Id. at 179, 113 S.Ct. at 1170 (footnote omitted, emphasis in original). Operation of the enterprise is not limited to its formal managers or employees because "[a]n enterprise might be 'operated' or 'managed' by others 'associated with' the enterprise who exert control over it as, for example, by bribery." Id. at 184, 133 S.Ct. at 1173. In Aetna the First Circuit found that defendants who, with the cooperation of two inside Aetna appraisers, had processed false insurance claims,

had exercised control over the victim insurance company:

[Defendants] caused the Aetna appraisers to approve false claims and conduct their appraisals in a manner contrary to Aetna's business practices and caused Aetna to pay out large sums of money on false claims. The evidence was sufficient to support a finding that [defendants] exerted control over the enterprise, if not by bribery . . . then at least by other methods of inducement.

Aetna, 43 F.3d at 1560.

Plaintiffs allege that the false inflation of AWP's caused the third-party payor victim-enterprises to pay more for prescription drugs than they otherwise would have paid. However, there is no allegation of infiltration of the third party payors, of cooperation by insiders, or of inducement of insiders, by bribery or any other covert means. The reporting of inflated AWP's to independent trade publications, which in turn resulted in the payment of inflated drug prices predicated on those prices, does not constitute "operation or management" of the third-party payor health programs within the meaning of § 1962(c). See In re Smithkline Beecham Clinical Labs., Inc., 108 F. Supp.2d 84, 100 (D. Conn. 1999) ("[A]lthough [defendant's] alleged fraudulent billing practices may have victimized the physicians' offices, hospitals, and laboratories, that does not suffice to establish that [defendant] 'operated or managed' the affairs of each of these alleged enterprises.") (emphasis in original); but see Liberty Mut. Ins. Co. v. Diamante, 138 F. Supp.2d 47, 61 (D.